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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.

EXAMINER

ART UNIT	PAPER NUMBER

7

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/557,262	ROSENBERG ET AL.	
	Examiner	Art Unit	
	Ram Shukla	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-60 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claims 1-60 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15)☐ Notice of References Cited (PTO-892)
16)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17)☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18)☐ Interview Summary (PTO-413) Paper No(s). _____ .
19)☐ Notice of Informal Patent Application (PTO-152)
20)☐ Other: .

DETAILED ACTION

1. Claims 1-60 are pending in the instant application.

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

It is noted that claimed invention in the instant application is drawn to six patentably distinct nucleic acid molecules with distinct nucleotide sequence and each nucleic acid encodes a distinct protein (a human or murine 3-OST1, human 3-OST2, human 3-OST3A, human OST-3B, human 3-OST4, and C.elegans ce-3-OST). For example, different 3-OSTs have different number of transmembrane domains, such as three transmembrane domains in 3-OST1 and 4 transmembrane domains in 3-OST2 and their substrates are also be different. Accordingly, each nucleic acid encoding a distinct 3-OST, vector comprising the nucleic acid, host cell comprising the vector and a transgenic animal expressing the 3-OST has been considered as a distinct group (groups I-VI). Likewise proteins, antibodies, reporter constructs and in vitro method relating to each OST protein has been has been placed in a distinct group.

SET I. Groups I-VI

Claims 1-12, and 29-32, drawn to an isolated nucleic acid encoding a full length or fragments of 3-OST protein, vectors comprising the nucleic acid, host cells comprising the vector, and a non-human transgenic animal that expresses an endogenous or exogenous 3-OST protein, classified in class 800, subclass 8.

SET II. Groups VII-XII

Claims 13-18, drawn to a 3-OST protein or a functional fragment thereof, classified in class 530, subclass 350.

SET III. Groups XIII-XVIII

Claims 19-28, drawn to an in vitro method of proteoglycan sulfation of a polypeptide by a 3-OST enzyme activity, classified in class 435, subclass 15.

SET IV. Groups XIX-XXIV

Claims 29-32, drawn to a transgenic non-human animal wherein the expression of an endogenous 3-OST gene is inactivated by inserting a reporter construct, in which the expression of the reporter gene is under the control of a 3-OST transcriptional regulatory sequence, in the genome of the transgenic non-human animal by homologous recombination, classified in class 800, subclass 8.

SET V. Groups XXV-XXX

Claims 33-36, drawn to an antibody specific to a 3-OST protein and a cell producing the antibody, classified in class 530, subclass 387.1.

SET VI. Groups XXXI-XXXVI

Claims 37-40 and 57-60, drawn to a nucleic acid which comprises the regulatory sequences of a 3-OST gene driving the expression of a reporter gene, a host cells comprising the nucleic acid, and a method of identifying compounds that can modulate the expression of a 3-OST gene wherein said compound alters the activity of a 3-OST transcription regulatory sequences, classified in class 435, subclass 375.

SET VII. Groups XXXVII-XXXXII

Claims 41-56, drawn to an in vitro method of partial sequence determination of a polysaccharide sample by monitoring ligand binding due to modification of the polysaccharide by a 3-OST, classified in class 435, subclass 4.

3. The inventions are distinct, each from the other because of the following reasons:

Inventions of the groups I-VI of SET I are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are nucleic acids that encode proteins that have different amino acid sequence

structure and different domain structure. While all the nucleic acids encode a 3-OST enzyme, they have different activity and substrate specificity, for example, 3-OST1 acts on GlcA to change it to GlcNS 3S $^{+}$ 6S, whereas 3-OST2 catalyzes the sulfation reaction of modifying a GlcA 2S to GlcNS 3S or GlcNS to GlcA2S to GlcNS 3S (see specification on 14, lines 3-12 and page 15, lines 3-9). Likewise, the inventions of the groups VII to XII of SET II are also not related to each other because the structure of each of these proteins is different due to the presence of different number of motifs, and therefore, their sequence structure would also be different and there function would also be different. The inventions of the groups XXV to XXX of Set V are patentably distinct each from the other because the antibody raised against the protein of one group may not recognize the protein of another group.

The nucleic acids of the set VI are patentably distinct each from the other because they would have different sequence structure and might have different regulatory domains and motifs. The nucleic acids of the sets VI are patentably distinct from each of the nucleic acids of the set I because they comprise transcriptional regulatory element compared to the coding sequences of set I (groups I-VI) and therefore they have distinct and different utilities and functions. For example, the utilities of cDNAs or coding sequences is to make proteins whereas the regulatory sequences are used for screening of gene expression modulatory compounds.

The compositions of the SETS I, II, and V are patentably distinct each from the other because they are materially different compositions, have different physical and chemical characteristics, and also have different utilities. For example, the physical and chemical characteristics of a nucleic acid are different from those of a protein or an antibody. Likewise, the utility of a nucleic acid is different from those of a protein or an antibody, for example, a nucleic acid is used for making probes that can be used for northern or southern hybridization, whereas protein can be used for enzyme activity studies while an antibody can be used for western blotting or in-situ hybridization. Additionally, the characteristics of an antibody can vary depending upon the epitope or motif used for raising the antibody.

The transgenic animals of the groups XIX-XXIV of the set IV are patentably distinct each from the other because inactivation of different 3-OST genes may results in different phenotypes and therefore, the utility of each of the animals would be different.

The transgenic animals of the Set IV would be patentably distinct from the transgenic animals of the set I because the animals of set IV lack a functional 3-OST protein compared to the animals of set I, which express these proteins. Therefore, the phenotype as well as the utilities of the animals of the set IV and set I would be different. For example, the animals of set I can be used for identifying compounds that modulate the enzymatic activity of 3-OST, on the other hand, the animals of set IV can be used for screening of compounds that modify the promoter activity of the 3-OST gene.

The methods of groups XIII-XVIII (set III) are patentably distinct each from the other because they use different 3-OST proteins that would have different enzymatic activities. Likewise the methods of the groups XXXVII to XXXXII are patentably distinct each from the other because the protein have different structure and a ligand which binds to the protein of one group may not bind to the protein of another. The methods of set III and set VII are patentably distinct each from the other because they have distinct method steps and use different components and therefore their reactants and products are different. For example, the methods of groups set III use only two components, a substrate for sulfation and the 3-OST enzyme. On contrary, the methods of set VII would require a polysaccharide of interest, a ligand that specifically binds the polysaccharide, and an agent that modifies the polysaccharide.

Inventions of the sets I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). The compositions of each of the groups sets II and III are related because they are drawn to different 3-OST proteins and in vitro enzyme assays using these proteins,

however, they are patentably distinct because the proteins have multiple uses, for example, for producing antibodies or as standards in western blotting or in vitro enzyme assay. The compositions of sets I, II, IV-VI are patentably distinct from methods of set VII because the method of the set VII would depend on a polysaccharide and a ligand binding to the polysaccharide. Alternatively, the method of the set VII can not be used for making the compositions of the sets I, II, and VI-VII.

4. Because these inventions are distinct for the reasons given above, have acquired a separate status in the art shown by their different classification and their recognized divergent subject matter, and because each invention requires a separate, non-coextensive search, restriction for examination purposes as indicated is proper.

5. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Applicants are advised to submit a clean version of each amended claim (without underlining and bracketing) according to § 1.121(c). For instruction, Applicants are referred to http://www.uspto.gov/web/offices/dcom/olia/aipa/index.htm.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ram R. Shukla whose telephone number is (703) 305-1677. The examiner can normally be reached on Monday through Friday from 7:30 am to 4:00 p.m. If attempts to reach the examiner by telephone are

unsuccessful, the examiner's supervisor, Karen Hauda, can be reached on (703) 305-6608. The fax phone number for this Group is (703) 308-4242. Any inquiry of a general nature, formal matters or relating to the status of this application or proceeding should be directed to the Kay Pinkney whose telephone number is (703) 305-3553.

Ram R. Shukla, Ph.D.

SCOTT D. PRIEBE, PH.D
PRIMARY EXAMINER